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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/697,546

10/30/2003

David W. Wynn

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27777 7590 09/10/2009  
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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/697,546	<b>Applicant(s)</b> WYNN ET AL.	
	<b>Examiner</b> MICAH-PAUL YOUNG	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-16, 18-22, 26, 27, 29-31, 36-42 and 47-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-16, 18-22, 26, 27, 29-31, 36-42 and 47-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/30/09, 6/3/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

**Acknowledgment of Papers Received:** Remarks/Amendment dated 5/15/09.

### ***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on 3/30/09 and 6/3/09 were filed in timely after the mailing date of the Specification on 10/30/03. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13-16, 18-22, 26, 27, 29-31, 36-42 and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Shah et al (USPN 6,126,969 hereafter '969) in view of Sakamoto et al (USPN 4,828,840 hereafter '840). The claims are drawn to a dosage form comprising an immediate release and sustained release portion, where the dosage form has a liquid vehicle forming a liquid suspension.

The '969 patent teaches a dosage form comprising an immediate release portion comprising uncoated drug particles, and an extended releasing portion, comprising coated drug

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particles (abstract). The dosage form comprises sweeteners and other excipients (col. 7, lin. 15-30). The extended release portion comprises coated core particles where the coating comprises water insoluble polymers such as ethylcellulose and cellulose acetate (col. 4, lin. 63-65, example). The coating comprises a combination of multiple polymers types and copolymers including film-forming polymers (col. 4, lin. 40-58). The active agents include various well-known drugs including ibuprofen and other NSAID's such as naproxen (col. 6, lin. 14-15). Another embodiment of the invention has the coated particles in a concentration of approximately 20.79% (table 1). The formulation comprises polyethylene glycol (Table 1 and 2). Regarding the therapeutic effect of the dosage form, it is the position of the Examiner that such limitations are inherent features of the composition. Regarding the liquid suspension limitation, the '969 patent is suggestive that the formulation (a combination of coated and uncoated particles providing a combination immediate and sustained release delivery) can be dispersed in water in order to form a suspension (col. 4, lin. 15-17). The reference is however, not explicit about the exact structure of the liquid suspension; it is the position of the Examiner that the concentrations would be similar to those of the controlled release formulation. It is the position of the Examiner that these concentrations represent an optimization of ranges and are not inventive barring a showing of unexpected results.

The reference is silent to the ratio of the water insoluble polymer relative to the enteric polymers recited in the instant claims. This ratio is well within the level of skill in the art as seen in the '840 patent. The '840 patent discloses a controlled releases formulation comprising a coated dosage form where the coating comprises a combination of water-insoluble polymers and enteric polymers (abstract). The formulation can last for longer than 10 hours (col. 2, lin 30-35)

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and can comprise a wide range of active agents. The film coating comprises water-insoluble polymers such as cellulose acetate, ethylcellulose and copolymers of polymethacrylate and trimethylammoniummethyl chloride methacrylate sold as Eudragit RS (col. 4, lin. 5-15). The enteric polymers include hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose succinate acetate and copolymers of methacrylic acid and polymethyl methacrylate (col. 4, lin. 16-25). The water-insoluble polymers are combined with the enteric polymers to form an extended release coating where the insoluble polymer is present in a ratio to the enteric polymer of 8.7:1 (example 13) within the limits of the instant claims.

Regarding the specific ratios and ranges of the instant claims, it remains the position of the Examiner that the prior art combination would obviate these limitations. The general conditions of the claims have been met by the combined prior art, namely a liquid suspension of particles comprising a portion of uncoated and a portion of coated particles is suspended in water. The coated particles comprise a combination of water insoluble and enteric polymers present in a ratio within the range of the instant claims. Applicant is reminded that when the general where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not

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patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Regarding the pKa of the at least one active agent contained in the sustained release particles and its relation to the pH of the suspension it is the position of the Examiner that the prior art inherently meets this limitation. It is the position of the Examiner that the pKa is a function of the structure of the instant invention, and is due to the arrangement of the immediate and sustained release particles. Since the prior art discloses the same arrangement of particles and components, the prior art must also possess the same pKa and pH limitations as the instant claims. The pKa and its relationship to the pH of the suspension is an inherent feature that cannot be separated from the components of the instant claims. In the instant claims the pKa of the NSAID is higher than the pH of the suspension, the NSAID is more acidic than that surrounding suspension. If ibuprofen (pH of 4.4) is suspended in water (pH of 7) then the claim limitation is met. As such since the prior art discloses a formulation meeting each of the compositional limitations it must also meet the functional limitations inherently.

With these things in mind it would have been obvious to combine the teachings and suggestions of the teachings and suggestions of the prior art in order to provide a stable liquid suspension. It would have been obvious to modify the ratio of polymers in the extended coating of the '969 patent as seen in the '840 patent in order to deliver a stable drug release over an extended period of time, at least 10 hours. It would have been obvious to combine the teachings and suggestions of the prior art with an expected result of a stable controlled release formulation useful in treating pain.

***Response to Arguments***

Applicant's arguments filed 5/15/09 have been fully considered but they are not persuasive. Applicant argues that:

**The combination of the '969 and '840 patents do not obviate the instant claims since the '969 patent does not disclose enteric polymers, and the combination does not teach or suggest the pKa limitation of the instant claims.**

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding this argument it remains the position of the Examiner that the combination continues to obviate the instant claims. Applicant continues to argue that the '969 patent does not teach enteric polymers, however enteric polymers are disclosed as useful in several locations throughout the disclosures. The '969 does prefer water insoluble polymers, over enteric polymers, however this preference is over enteric polymers alone. Col. 4, lin. 59-col. 5, lin. 22 discloses several enteric polymers, as well as a water insoluble polymers. Eudragit methacrylate copolymers are used in the examples, these can include either enteric polymers or not. The '969 patent suggests the use of water insoluble, pH independent polymers, but does not foreclose the inclusion of enteric polymers completely. Taking the disclosures as a whole the artisan of ordinary skill would be motivated to use a coating composition comprising at least the water insoluble polymers of the '969. The artisan of ordinary skill would be motivated to look to the '840 patent since this patent discloses similar polymers coating a drug compound. The '840

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patent provides the specific combination of water insoluble polymers (similar to those of the '960 patent ) and enteric polymers (also disclosed in the '969 patent). The '840 patent discloses a coated sustained release formulation comprising ethylcellulose and hydroxypropylmethylcellulose phthalate in a ratio of about 8:1 (Example 13). As discussed above it would have been obvious to include this combination of the polymers into the formulation of the '969 patent since both patents disclose similar polymers as useful in the controlled release coating portion. Regarding the newly added pKa limitation, as discussed above since the formulation is suspended in water (pH of 7) the ibuprofen of the particles would be more acidic having a higher pKa than the suspending liquid.

For these reasons the claims remain obviated.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/  
Examiner, Art Unit 1618